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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/053,535

01/15/2002

Augustine M. Choi

13681-003002

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

06/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/053,535	<b>Applicant(s)</b> CHOI ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 6/26/2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-47, 50, 53-59, 62-89, 96-99, 102-115 and 118-158 is/are pending in the application.
- 4a) Of the above claim(s) 79-88 is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 43-47, 50, 56-59, 62-78, 89, 96, 97, 105, 107, 109, 111, 115, 119, 124, 128, 132, 136 and 140-158 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims allowed are 53-55,98,99,102-104,106,108,110,112-114,118,120-123,125-127,129-131,133-135 and 137-139.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
20070129,20070601,20070828, 20070913, 20071002, 20071213

### **DETAILED ACTION**

Claims 53-55, 98,99, 102-104, 106, 108, 110, 112-114, 118, 120-123, 125-127, 129-131, 133-135, 137-139 appear to be allowable.

The Examiner notes that the Rule 1.132 Declaration of Dr. Leo Otterbein was altered on the signature page by a patent agent or patent attorney, however, said alteration was not initialed and dated by the declarant. As such, the examiner requests that Applicant obtain the same or provide a new declaration properly dated and signed by the declarant.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-47, 50, 56-59,62-78, 89, 96, 97, 105, 107, 109, 111, 115, 119, 124, 128, 132, 136, 140-158 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhalation of gaseous carbon monoxide to treat the claimed conditions and diseases, does not reasonably provide enablement for treatment of the same by methods of administration other than inhalation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

#### ***The nature of the invention:***

The invention is directed to treatment of various conditions and diseases by administration of carbon monoxide.

#### ***The state of the prior art and the predictability or lack thereof in the art:***

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The prior art does not appear to disclose treatment of the claimed diseases and conditions. As such, predictability in the art appears to be low.

*The amount of direction or guidance present and the presence or absence of working examples:*

Although the Specification describes gaseous carbon monoxide and compositions which are not gaseous, the working examples in which a patient, i.e. an animal model, is treated only inhaled carbon monoxide is used. The lungs are uniquely designed to provide exchange of gases. There is no evidence that there would sufficient gas exchange, either of gaseous carbon monoxide or carbon monoxide dissolved in a vehicle, across the intestinal wall to provide effective treatment of the claimed disease or conditions. See e.g. Wing-Gaia et al., pg 686 (no difference in blood gas after ingestion of oxygenated water).

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that that encompass other routes of administration other than by inhalation. As such, one of ordinary skill in the art would be required to do undue experimentation in order determine what other methods of administration would be effective in treating the claimed disease and conditions.

The Examiner has duly considered that Applicant's arguments but deems them moot in light of the new grounds of rejection. The Applicant appears to have provided sufficient evidence showing that inhaled carbon monoxide would be effective in treating necrotizing enterocolitis. However, since none of example and evidence appears to show that other methods of administration would be effective in treating the claimed disease or conditions and the lungs, unlike the intestinal tract of humans, are uniquely designed to effect the exchange of gases,

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evidence which employs inhaled carbon monoxide is not sufficient to show enablement of the entire scope of the claims.

### *Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
June 13, 2008

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616